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EXAMINER	
SEIDMAN, S	#6
ART UNIT	PAPER NUMBER
127	

DATE MAILED: 12/15/86

This is a communication from the examiner in charge of your application.

COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☐ Responsive to communication filed on _____ ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), ___ days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☒ Notice of References Cited by Examiner, PTO-892.
2. ☐ Notice re Patent Drawing, PTO-948.
3. ☐ Notice of Art Cited by Applicant, PTO-1449
4. ☐ Notice of informal Patent Application, Form PTO-152
5. ☐ Information on How to Effect Drawing Changes, PTO-1474
6. ☐ _____

Part II SUMMARY OF ACTION

1. ☒ Claims 1-40 are pending in the application.
   Of the above, claims 4, 9-16 and 22-40 are withdrawn from consideration.
2. ☐ Claims _____ have been cancelled.
3. ☐ Claims _____ are allowed.
4. ☒ Claims 1-3, 5-8, and 17-26 are rejected.
5. ☐ Claims _____ are objected to.
6. ☒ Claims 1-40 are subject to restriction or election requirement.
7. ☒ This application has been filed with informal drawings which are acceptable for examination purposes until such time as allowable subject matter is indicated.
8. ☐ Allowable subject matter having been indicated, formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. These drawings are ☐ acceptable; ☐ not acceptable (see explanation).
10. ☐ The ☐ proposed drawing correction and/or the ☐ proposed additional or substitute sheet(s) of drawings, filed on _____. has (have) been ☐ approved by the examiner. ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed _____, has been ☐ approved. ☐ disapproved (see explanation). However, the Patent and Trademark Office no longer makes drawing changes. It is now applicant's responsibility to ensure that the drawings are corrected. Corrections MUST be effected in accordance with the instructions set forth on the attached letter "INFORMATION ON HOW TO EFFECT DRAWING CHANGES", PTO-1474.
12. ☐ Acknowledgment is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____; filed on _____.
13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

PTOL-326 (Rev. 7-82) EXAMINER'S ACTION

Applicant is encouraged to submit copies of all prior art known to applicant to meet the requirements of 37 CFR §1.56 and a completed form PTO-1449, "List of Prior Art Cited by Applicant".

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-3, 5-8 and 17-26, drawn to DNA and cDNA encoding HTLV-III, peptides encoded thereby, vectors containing the cDNA, host cells transformed by the vectors, and use of the transformed host cells to produce polypeptides, classified in Class 435, subclass 317.

II. Claims 4 and 11-13, drawn to polypeptides and hybrid peptides per se, classified in Class 530, subclasses 300 and 350.

III. Claims 14-16, drawn to RNA transcripts, classified in Class 435, subclass 68.

IV. Claims 27-37 and 40, drawn to antibodies, assays employing antibodies, tests for the presence of antibodies, and hybridomas for producing antibodies, classified in Class 424, subclass 85.

Claims 9, 10, 38 and 39, drawn to a method for detecting a nucleic acid and DNA probes used in the test, classified in Class 435, subclass 6.

The inventions are distinct, each from the other, because of the following reasons:

Inventions I and II, III, IV and V are related as species in an intermediate-final product relationship.

Distinctness is proven for claims in this relationship if the intermediate product is useful other than to make the final product (MPEP 806.04(b), 3rd paragraph), and the species are patentably distinct. (MPEP 806.04(h)).

In the instant case, the intermediate product is deemed to be useful as a reagent in a diagnostic assay and the inventions are deemed patentably distinct since there is nothing on this record to show them to be obvious variants. Additionally, the RNA transcripts and the peptides may be isolated from the virus, the hybrid peptides and DNA probes may be synthesized chemically, the antibodies may be isolated from human sera, and the hybridoma may be produced using those antibodies.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103 of the other invention.

During a telephone conversation with Dr. Granahan on 10/14/86 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-3,

5-8 and 17-26. Affirmation of this election must be made by applicant in responding to this Office action. Claims 4, 9-16 and 27-40 are withdrawn from further consideration by the examiner as being drawn to a nonelected invention. See 37 CFR 1.142(b).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant should note that the restriction requirement has been slightly modified. This modification does not change the substance of applicant's election.

Claims 1-40 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-48 of copending application serial no. 693866. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims encompass virtually identical subject matter.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

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The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. 112, first paragraph, as failing to provide an adequate written description of the invention and failing to provide an enabling disclosure.

The invention appears to employ novel microorganisms, such as OmpA and pHR100, which were not deposited. It is not clear if the written description is sufficiently clear to avoid the need for a deposit, which must meet the criteria set forth in MPEP 608.01(p)(C). Applicant may provide assurance of compliance with the requirements of §112 in the form of a declaration avering that:

(a) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;

(b) that all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;

(c) that the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the effective life of that patent, whichever is longest; and,

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(d) that the deposit will be replaced if it should ever become non-viable or mutate.

Claims 1-3, 5-8 and 17-26 are rejected under 35 U.S.C. 112, first paragraph, for the reasons set forth in the above objection to the specification.

Claims 1-3, 5-8 and 17-26 are rejected under 35 U.S.C. 112, first paragraph, as the disclosure is enabling only for claims limited to bacterial hosts cells and plasmid vectors used for expression therein and to cDNA encoding the env, and env-lor regions of HTLV-III. See MPEP 706.03(n) and 706.03(z).

Applicant does not teach the requisite transcriptional and translational control signals requisite to achieve expression in all host cells.

The signals necessary to achieve expression as a cloned gene in a prokaryotic host cell are vastly different from those necessary to achieve expression of a cloned gene in a eukaryotic host cell. Additionally, not all genes may be expressed in all host cells. It would, therefore, require undue experimentation for one of ordinary skill in the art to clone all of the genes encompassed by the claims in host cells other than the bacterial cells disclosed in the specification. Thus, the claims are broader than the enabling disclosure.

See, e.g. Ex parte Forman 230 USPQ 546. The claims are also broader than the enabling disclosure in that they read on all immunoreactive peptides expressed by cells transformed with recombinant vectors containing any HTLV-III cDNA. Applicant does not teach all the peptides that are encoded by HTLV-III nor does applicant teach vectors and host containing cDNA encoding all the peptides. For example, applicant does not teach the TAT-III gene, which was identified by inventors not named instant application.

Claims 1-7, 13-16, and 32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-7, and 13-16 are indefinite in the recitation of "immunoreactive" because it is unclear whether "immunoreactive" encompasses peptides for which antibodies are naturally found in human sera or peptides that are capable of eliciting an immune response in any organism. Claim 32 is indefinite in failing to provide proper antecedent basis for "fusion protein".

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless-

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claims 1-3, 5-8 and 17-26 are rejected under 35 U.S.C. 103 as being unpatentable over Gallo et al. and Schupbach et al. and Suggs et al.

Schupbach teaches that sera from AIDS patients, reactive with nine HTLV-III encoded antigens and that HTLV-III is a member of the HTLV family because of

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genome of HTLV-III and identified the open reading frames, which could then have been compared to the Western blots of Gallo and Schubbach as well as the HTLV map generated by Seiki in order to identify the HTLV-III DNA regions encoding the antigens and to have constructed DNA probes for regions encoding the cloning the genes encoding each antigen.

Claims 17-26 are rejected under 35 U.S.C. 103 as being unpatentable over Gallo and Schupbach and Suggs and Seiki as applied to claims 1-3, 5-8 and 17-26 above, and further in view of Weinstock et al.

Gallo and Schubbach and Suggs and Seiki are applied as above. Weinstock teaches open reading frame expression vectors for antigen production in E. coli using protein fusions to beta-galactosidase.

It would have been obvious to one having ordinary skill in the art to have expressed the cloned genes in bacterial host cells as taught by Weinstock.

Any inquiry concerning this communication should be directed to Dr. S. Seidman at telephone number 703-557-5137.

THOMAS G. WISEMAN
SUPERVISORY PATENT EXAMINER
ART UNIT 127

SS:Seidman:bjk
11/25/86
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